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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,330

09/12/2005

Gary N. Mills

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

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3736

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,330	<b>Applicant(s)</b> MILLS ET AL.	
	<b>Examiner</b> Brian Szmaj	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4-6 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Levin et al (7,354,417 B1).

Levin et al disclose a means for measuring the volume of fluid in the peritoneal cavity and further disclose providing a first set of injection electrodes (IRU, ILU, IRL, ILL) and a second set of measurement electrodes (MLL, MRL, MLB, MRB); positioning members of the first set of electrodes on an external surface of the body to introduce electric current flow through the mammalian tissue and thereby establish flow paths that define injection vectors along which electric currents flow between two or more injection electrodes (the multiple injection electrodes inject current at different positions (vectors) on the surface of the body); positioning members of the second set of electrodes on the body to define measurement vectors relating to electrical voltages produced in response to the electrical currents flowing between the injection electrodes, the injection and measurement vectors defining an anatomical space of the mammalian tissue (the measurement electrodes measure the current from the different injection vectors, and the current and measurement vectors define the peritoneal cavity); deriving from each

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of different pairs of the injection and measurement vectors two or more bioimpedance values that is characteristic of indicating the bioimpedance of body tissues and fluids within a region of the anatomical space (see Column 5, lines 4-7); analyzing the two or more electrical bioimpedance values to detect a presence of a volume of fluid or a change in a volume of fluid for indications of fluid movement, accumulation, or depletion affecting the region in the anatomical space (see Column 2, lines 6-9); analyzing the bioimpedance values entails determining differences in the bioimpedance values derived from the injection and measurement vectors (see Summary); determining temporal changes in the bioimpedance values derived from the injection and measurement vectors (see Summary); the injection and measurement vectors define a nominal shape of the anatomical space in the presence of a nominal quantity of fluid, and in which the presence of other than the nominal quantity of fluid changes the anatomical space from its nominal shape (see Summary; pre-dialysis quantity of fluid would represent a change in nominal shape, and post-dialysis quantity of fluid would represent a nominal shape); analyzing the bioimpedance values to determine the extent of fluid volume in the mammalian tissue (see Summary; bioimpedance measurement for dialysis treatment); and the fluid includes blood, and further comprising analyzing the electrical impedance values to determine whether the presence of a volume of blood indicates an accumulation or loss of blood (see Summary; dialysis fluid level measurement using bioimpedance). See also Figures 1-3.

***Claim Rejections - 35 USC § 103***

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al (7,354,417 B1) as applied to claim 1 above, and further in view of Baura et al (6,561,986 B2).

Levin et al, as discussed above, disclose a means of measuring the bioimpedance of tissue to determine the presence of edema via the application of a current and the measurement of the resulting voltage, but fail to disclose the current flow is introduced by a complex electrical current waveform and the analyzing of the bioimpedance values includes chirp transform analysis or waveform analysis; each member of the first set includes a current source and a current sink, the current source and current sink being positioned at locations on the body such that electrical current flowing from one current source on one member flows to the current sink of another member; and each member of the first set includes a plurality of current sources and a plurality of current sinks.

Baura et al disclose a means for determining a hemodynamic assessment and further disclose the current flow is introduced by a complex electrical current waveform and the analyzing of the bioimpedance values includes chirp transform analysis or waveform analysis (see Figure 12; Column 19, lines 30-67-Column 21, lines 1-54); each member of the first set includes a current source and a current sink, the current source

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and current sink being positioned at locations on the body such that electrical current flowing from one current source on one member flows to the current sink of another member; and each member of the first set includes a plurality of current sources and a plurality of current sinks. See Column 19, lines 39-45 and Column 20, lines 8-11. The disclosure of applying a current to some of the terminals, also discloses the terminals that are not used would operate as a "current sink" since the current would flow to the unused electrode.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Levin et al to include the use of a complex current waveform, chirp waveform analysis or waveform analysis, and the use of current sinks, as per the teachings of Baura et al, since it would provide a means of measuring fluid in the peritoneal cavity with fewer electrodes while acquiring a more accurate bioimpedance measurement.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke (3,452,743) as applied to claim 1 above, and further in view of Takehara et al (2002/0022787 A1) in view of Duong et al (6,740,518 B1).

Rieke, as discussed above, disclose a means for measuring the body impedance of a subject but fail to disclose the electrical current flow is introduced at multiple signal frequencies and the analyzing of the electrical bioimpedance value includes Fourier analysis and data reduction.

Takehara et al disclose a means for measuring body water concentration via multi-frequency bioimpedance measurements and further disclose the electrical current flow is introduced at multiple signal frequencies. See Paragraphs 0039-0046.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Rieke to include the use of multi-frequency currents, as per the teachings of Takehara et al, since it would provide a means of more accurately determining any changes in the tissue impedance based on the increased applied current.

Rieke and Takehara et al however fail to disclose analyzing the acquired data through the use of Fourier transform and data reduction.

Duong et al disclose a means for detecting analytes and further disclose analyzing the acquired data through the use of Fourier transform and data reduction. See Column 86, lines 48-51; and Column 89, lines 1-21.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Rieke and Takehara et al to include the use of Fourier transform and data reduction, as per the teachings of Duong et al, since it is well known in the art to utilize data analysis methods such as Fourier transform and data reduction when dealing with acquired impedance measurements.

### ***Response to Arguments***

6. Applicant's arguments, filed August 5, 2009, with respect to the rejection(s) of claim(s) 1, 7 and 8 under Rieke (3,452,743) have been fully considered and are

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persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Levin et al (7,354,417 B1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmál whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmál/  
Examiner, Art Unit 3736